DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Hitachi Medical Systems America, Inc.
% Mr. Doug Thistlewaite
Manager of Regulatory Affairs
1959 Summit Commerce Park
TWINSBURG OH 44087

March 6, 2015

Re: K143537
Trade/Device Name: Sirius Starmobile tiara
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: December 9, 2014
Received: December 15, 2014

Dear Mr. Thistlewaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143537

Device Name
Sirius Starmobile tiara

Indications for Use *(Describe)*
The Mobile X-ray Unit Sirius Starmobile tiara is a general radiography system and is composed of the X-ray high voltage generator, X-ray tube, support unit, and digital radiograph device (DR-ID 800) made by Fujifilm Corporation.

This device is designed for pediatric and adult patients.

It is intended for use in general radiography of the head, body, or extremities including pediatric exams. The device output can provide an aid to diagnosis when used by a qualified physician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Submitter Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371 ph: (330) 425-1313 fax: (330) 963-0749
Contact:	Douglas J. Thistlethwaite
Date:	December 9, 2014

Device Name

Regulation Number:	21 CFR 892.1720
Regulation Name:	Mobile X-ray System
Product Code	IZL-System, X-ray, Mobile
Trade/Proprietary Name:	Sirius Starmobile tiara System
Predicate Device(s):	Carestream DRX-Revolution Mobile X-ray System (K120062)

Device Intended Use

The Mobile X-ray Unit Sirius Starmobile tiara is a general radiography system and is composed of the X-ray high voltage generator, X-ray tube, support unit, and digital radiograph device (DR-ID 800) made by Fujifilm Corporation.

This device is designed for pediatric and adult patients.

It is intended for use in general radiography of the head, body, or extremities including pediatric exams. The device output can provide an aid to diagnosis when used by a qualified physician.

Device Description

The Sirius Starmobile tiara battery powered, mobile x-ray system features a built-in Flat Panel Detector System: DR-ID800 which is a modification of the FDR D-EVO Flat Panel Detector System (DR-ID600), K132509. Because the Flat Panel Detector System is incorporated in the mobile equipment, the images are available to the technologist in a very short time, allowing the technologist to assure the exam has been performed adequately, minimizing return trips. Wireless communication is available, as an option, for updates to the patient worklist from the RIS/HIS.

The Sirius Starmobile tiara provides smooth and quiet motorized travel capability via rear wheels independently driven by dual motors, a versatile radiography range through the pantograph arm, and easy-to-operate positioning of flat detector providing sharp image quality with a short exam completion time.

Device Technological Characteristics

The Sirius Starmobile tiara is substantially equivalent to the predicate device, the Carestream DRX-Revolution Mobile X-ray System. The Sirius Starmobile tiara and the Carestream DRX-Revolution Mobile X-ray System both consist of an x-ray generator, x-ray tube, collimator, and graphical user interface on an operator console with touch screen monitor. These components are mounted on a motorized cart that is battery powered to enable the device to be moved from location to location. Both systems utilize a digital flat panel detector for image capture and can also be used to expose CR storage phosphor or film cassettes. Both systems have operator console software with image processing capability.

Summary of Clinical/Non-Clinical Testing

Non-Clinical Testing

The Sirius Starmobile tiara was subjected to the following laboratory testing:

- AAMI ANSI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012

  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 3: 2007

  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-3 Edition 2.1 2013

  Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6 Edition 3.1 2013

  Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance Collateral standard: Usability
- IEC 60601-2-28 Edition 2.0 2010

  Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-54 Edition 1.0 2009

  Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 62304 Edition 1.0, Medical device software - Software life cycle processes

Clinical Testing

The Sirius Starmobile tiara System submission includes sample clinical images in Section 10_ Performance.

Substantial Equivalence

Both the Sirius Starmobile tiara System (subject device) and the predicate device have the identical intended use for examinations of adult and pediatric patients over all parts of the body.

The key technological characteristics between the subject device and the predicate are substantially equivalent.

In regards to the x-ray tube, the subject device has a larger target angle, but the focal spot size is the same as the predicate, so beam coverage is equivalent. Anode heat capacity is less, but in mobile use the number of exams are less than conventional x-ray, so the lower heat capacity will not impact the ability to perform exams.

X-ray tube head movement is comparable between the subject device and the predicate. The maximum SID to floor is similar, but the subject device has a wider range of movement from the floor. While tube arm reach is slightly less than the predicate, all other motions of the subject device have a wider range.

All the detectors available for the subject device have comparable sizes to the predicate. Detector pixel size of the subject device (0.150mm) is within the typical range for general radiography (0.139 to 0.200mm). Section 10, Performance, shows bench test results and sample clinical data indicating that the subject device covers the range of body and extremity imaging, with acceptable image quality, as compared to general mobile radiography applications available on the predicate device and others in its class.

Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. the Sirius Starmobile tiara is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the Carestream DRX-Revolution Mobile X-ray System (K120062).